Site Specific Assessment (SSA) Form Guidelines

Purpose of the SSA Form
The purpose of the SSA Form is to enable applicants to provide sufficient detail about the research project to enable the Chief Executive or their delegate to make an informed decision about the acceptability of the proposal to a particular SA Health Organisation.

When the SSA Form should be used
The SSA Form should be used for site specific assessment of research projects involving more than low risk to participants, and where the research proposal has been submitted for ethical and scientific review using the National Ethics Application Form (NEAF).

The SSA process considers the following:

- Adequate resources (financial, human, equipment and infrastructure) for the research to proceed at the site and identified as appropriate, accountable and available;
- Researchers have the necessary expertise and experience; if not, relevant training is planned before carrying out their role in the research study
- Compliance with relevant laws, policies and codes of conduct relating to matters such as privacy, confidentiality, consent, bio-safety, professional standards, and radiation safety.

Importantly – the *Actual Monetary* and *In Kind* costs for the research study are to be provided in a budget, separate from the SSA, and approved by the research business manager / financial advisor. Failure to do so may prevent authorisation of the research at the nominated site.

This form must be completed for each site (i.e. each facility, location or service) under the control of a SA Health Organisation at which the research project is being conducted.

Creating an SSA Form
The Principal Investigator must create an SSA Form for each site at which the research project is being conducted. To create an SSA form in www.ethicsform.org/au

1. Ensure that your NEAF is open and click on the 'SSA' tab.
2. This will take you to the 'SSA' screen; once there, enter the number of forms you wish to create in the box and click on 'Create a new SSA'.
3. Select the form you wish to open; you will be prompted to nominate which state the site is located in; select 'South Australia'.
4. You will be prompted to nominate the type of form you wish to create; select 'SSA'.
5. Transfer one form to each Principal Investigator involved in the research project. For detailed guidance on how to transfer the form, select 'How to' from the 'Help' menu (to see an on-line demonstration); or select 'User manual' from the 'Help' menu (to download the user manual).
6. Do not generate a submission code for the SSA Form before sending it to the Principal Investigator.

For further information see the User Manual on the www.ethicsform.org/au website

Completing the SSA Form
The SSA Form must be completed by the Principal Investigator responsible for the research project at the site. All questions on the form must be completed

Detailed question-specific guidance is provided below. If you are still unsure about what is required, you should seek clarification from the Research Governance, IP & Contracts Office on 82223890 or rgipc@health.sa.gov.au

Submitting the SSA Form

1. When your SSA Form is complete, ensure that the form is open and click on the navigate icon.
2. This will take you to the 'Navigate' screen; once there, click on the 'Submission' tab.
3. This will take you to the 'Submission' screen; once there, click on the 'Generate submission code' button.
4. Once you have generated a submission code, download and print a copy of the form for review and submission by clicking on 'Generate PDF'.
5. Once the form has been finalised and printed, you will need to obtain the required signatures on the declaration pages.
6. Any supporting documents to be submitted with the application must be electronically uploaded at this time. **Do not upload agreements.** Draft Agreements must be emailed to the Research governance Office for review. Click on 'My *projects'*, '*Existing projects'*. On the relevant SSA Form click on *'Manage'* , *'Documents'* and then *'Upload'* and then upload all the relevant files from your computer. This ensures that the Research Governance Office receives all the supporting documentation.
   For further information on what documents are required to be uploaded see the Research Governance Checklist at http://www.rah.sa.gov.au/rg/research-governance.php

Please note

- Principal Investigators are advised to discuss / email their SSA with the Research Governance Office, before generating a submission code and submitting the SSA Form.
- Generating a submission code does not submit the application to the Research Governance Office; it saves the form and generates a submission code which then appears on each page of the form.
- A copy of the form printed before you have generated a submission code cannot be processed.
- Hard copies of the application and associated documents must be sent to the Research Governance Office for review and approval.
- Only applications signed with original signatures and the same submission code on the bottom of each page and will be accepted.

What happens next?

The Research Governance Office will assess whether the application is valid (complete) and ready for review. If the application is valid, the Research Governance Office will inform the Principal Investigator of the timeframe in which the application will be reviewed.

If the application is invalid, the Research Governance Office will inform the Principal Investigator in writing of the reasons why the application is invalid, and/or may request additional information.

When review of the SSA Form is completed, the Research Governance Office will make a recommendation to the Chief Executive or their delegate as to whether the project should be authorised, not authorised or requires Chief Executive/delegate consideration.

Following consideration by the Chief Executive or their delegate, the Research Governance Office will notify the Principal Investigator whether or not the project is authorised for commencement at the site.

Site Specific Assessment Application Form

1. Site Name

Please select

The Principal Investigator should list the site to which this site-specific assessment relates.
Please select “Royal Adelaide Hospital” if the study is to be performed at the RAH site.

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2. Name of Lead (reviewing) HREC:

Royal Adelaide Hospital Research Ethics Committee (EC00192)

Please select one of the SA Health ethics committees reviewing the ethics application

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3. Project Title

3a. Full Project Title: ☑ Populate from NEAF

3b. Short Project Title: ☑ Populate from NEAF

This information will be automatically populated from the NEAF

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4. Type of Research:

- ☐ Single Site
- ◉ Multi Site within South Australia only
- ☐ Multi Site across Australia

If Multi Site, please list additional sites where research is occurring:

For multi-centre research list all the sites.
Note: a separate SSA must be completed for each site at which the research is to be conducted.

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5. NHMRC Research Group

<please select>

A research project or research program should be allocated to a single type of activity. If the project or program is large and involves multiple types of activity, then the main relevant activity category should be identified.
Refer to NHMRC website for NHMRC Fields of Research.
http://www.nhmrc.gov.au/grants/policy/australian-standard-research-classifications-and-nhmrc-keyword-/-phrases

6. Site Principal Investigator/Coordinator

6a. Select Principal Investigator for this site.

Title: Forename/Initials: Surname:

Mailing Address:

Phone (BH):

Suburb/Town:

Mobile*:

State:

Postcode:

Fax:

Country:

E-mail:

6b. Is this person the principal contact person for the site?

Yes No

This section relates to the Principal Investigator involved in the project at the site.
All other researchers at the site should be recorded as Associate Investigators.

The easiest way to enter researchers into this section is to go to "My Contacts" on the top of the SSA page. Create a contact for each of the researchers associated with the project (include the researcher's own details). Then in the SSA Form, when details of researchers are requested, simply click on the icon (which looks like a letter box or a book with a bookmark) and this will take the researcher to the Contact List. Select one person at a time from the list, click on "View" and check that the contact details are correct. Then click on "Copy Details into the Form". The contact details will upload into the form. The Contact List is attached to the researcher's account, not to the application, so the list can be used for all subsequent applications.

If the Principal Investigator or Associated Investigators are not employed by the Royal Adelaide Hospital, a confidentiality agreement / code of conduct will need to be signed. Please contact the Research Governance Office for further information and forms.

7. Project Contact Person

Title: Forename/Initials: Surname:

Mailing Address:

Phone (BH):

Suburb/Town:

Mobile*:

State:

Postcode:

Fax:

Country:

E-mail:

This contact may be the clinical trial coordinator
Please ensure that the contact person you have indicated within the '*Contact Person for this Research Project'* section is the person you wish to have as the SOLE contact for all correspondence to and from the Research Governance Office regarding this SSA.
It is important to have one point of contact to avoid duplication and confusion.

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8. Project Description

☑ Populate from NEAF

This information will be automatically populated from the NEAF

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9. Project Start and Finish Dates

☑ Populate from NEAF

Start date: *(dd/mm/yyyy)*

Finish date: *(dd/mm/yyyy)*

This information will be automatically populated from the NEAF
However, these dates may be altered to accommodate different start up dates site to site.

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10. Departments / Services to be involved in the Research at this Site

	Department / Service	Contact Name	
1			
Add Row			

(Note that approval from the Head/s of Department/s or Service/s is required, and their signature should appear at the end of this form to verify their authorisation of the project to be conducted, and that all resources required to complete the project are available or will be made available at the site.)

It is highly recommended that Principal Investigators (and sponsors if applicable) contact the relevant supporting departments prior to HREC submission, to ensure that the services / samples etc, can be provided by the department. Principal Investigators should request a quote from the department / services where resources are required, prior to submission of the SSA.

Non standard of care pathology: contact dimitrios.zissis@health.sa.gov.au

Nuclear Medicine: contact barry.chatterton@health.sa.gov.au or max.bellon@health.sa.gov.au

Pharmacy: contact peter.slobodian@health.sa.gov.au

Radiology: contact julie.olsen@health.sa.gov.au

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11. Research Personnel Expertise

Briefly summarise the key expertise, experience and training of the local Coordinating/Principal Investigator and his/her research staff relevant to the proposed research *(note that a current CV of the Coordinating/Principal Investigator needs to be submitted with this application).*

List the PI and each of the Associate Investigators and briefly state their expertise and experience.
A current CV (2 page maximum) must be provided for each investigator involved in the study at the site. The Research Governance Office requires an updated CV per calendar year.
The PI should also list the training needs for the site to which the SSA relates.
e.g. sponsor will provide GCP training related to this study
e.g. sponsor will provide information about the investigational product and procedures

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12. Participant Recruitment

12a. Please specify anticipated number of participants to be recruited at this site.

12b. Please indicate what population groups the participants will be drawn from, and what methods will be used to recruit these participants.

Please attach a copy of any project advertisements/flyers to be used for recruitment purposes.

The Principal Investigator should identify the probable categories/participant group/s that will be recruited for the site to which the SSA relates.
It is important to indicate whether your participants will include those from particular or vulnerable groups, (Refer to the NHMRC National Statement of Ethical Conduct) as the type of expertise required of researchers will vary according to the needs of different participant groups. Provide any supplementary information that you feel is necessary.

The Principal Investigator should describe how potentially eligible participants will be identified and contacted at the site.

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13. Access to Information and Data

13a. Will this project require access to confidential information or data held by SA Health or a body incorporated under the *Health Care Act* (2008)?

☐ Yes ☐ No

13b. If so, what is the nature of this data?

13c. Has approval been sought from the data custodian/s to determine whether the required data will be made available? *(note that the signature of an appropriate authorising officer will be required at the end of the form)*

☐ Yes ☐ No

This is for access to information and data above normal standard of care

All research and evaluation proposals initiated or conducted by SA Health staff and/or external researchers seeking access to SA Health data and/or clients held centrally by SA Health (e.g. OACIS, ISAAC, Cancer Registry Data) must obtain SA Health approval. Contact the SA Health Ethics committee at hrec@health.sa.gov.au.
All research proposals that require access to other confidential information / data bases / registry's / tissue samples held by a SA Health Organisation must obtain approval by the appropriate authorised person. Researchers must consult with the data custodians prior to applying for ethics approval to ensure that relevant data items are available and that there are adequate local resources available to the data custodian to be able to provide that data for the specified study. Evidence of this consultation and confirmation that the necessary data is available, should be included in the ethics application.

http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Publications+and+resources/Policies+and+guidelines

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14. Intellectual Property

14a. Is it likely that new Intellectual Property will be developed as a result of this project being undertaken at this site?

☐ Yes ☐ No

14b. If so, Please outline what arrangements have been made regarding ownership of IP? *Note that IP arrangements should take account of the Whole of Government Intellectual Property policy (South Australia), and the SA Health Monetary Rewards Framework.*

14c. If Intellectual Property rights will be retained by the local Principal Investigator or Institution, please indicate who will be responsible for financially supporting the development of this IP should the research generate new knowledge or breakthroughs (e.g. drug development costs or patents).

14d. If Intellectual Property arrangements propose variations from the SA Health Monetary Rewards Framework, has the Business Manager (Intellectual Property) SA Health been consulted?

☐ Yes ☐ No

(If YES please attach evidence)

Note: Clause 12 of the sponsored clinical trial agreement states arrangements for the use of existing Intellectual Property (IP) and the ownership of new IP.

If there is a possibility of new IP being developed from this project and the Research Agreement does not state arrangements for the use of existing IP and the parties' rights in relation to ownership and use of all new IP developed through the research, then contact the Research Governance Office. Please also refer to the SA Whole of Government Intellectual Property Policy (SA Health Monetary Rewards Framework).

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15. Clinical Trials Information

15a. Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

☐ Yes ☐ No

15b. Is the medicine Australia Standard Indemnity Form(s), signed by the sponsor attached?

☐ Yes ☐ No ☐ N/A

15c. Is the Medicines Australia Standard Clinical Trial Agreement(s) signed by the sponsor attached?

☐ Yes ☐ No ☐ N/A

CTN/CTX forms

Further information on both the CTN and CTX schemes and completion of CTN/CTX forms is available at http://www.tga.gov.au/ct/index.htm

Indemnity
If a standard Medicines Australia CTRA is used indemnity arrangements are covered in Schedule 3 of the CTRA. The Medicines Australia Standard Indemnity Form referred to in this section is used, or the Medicines Australia Form of Indemnity – HREC Review only

Refer to http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/

For non standard studies and agreements, indemnity and insurance provisions for the study should be discussed with SA Health's Manager, Insurance Services.

A Checklist is available at http://www.rah.sa.gov.au/rg/research-governance.php

Industry sponsored studies CTRA:
For industry sponsored studies where the company has accepted all the roles of the sponsor the "*Clinical Trial Research Agreement - Medicines Australia Standard Form*" should be used.

Contract Research Organisation (CRO) CTRA:
Where the Contract Research Organisation (CRO) has accepted all the roles of the Sponsor the "*Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor*" should be used.

Collaborative Group Sponsored CTRA:
In the case of a collaborative sponsored clinical trial, the "*Clinical Trial Research Agreement - Collaborative or Cooperative Research Group (CRG) Studies*" should be used.

Phase IV CTRA:
For post marketing surveillance Phase IV studies the "*Clinical Trial Research Agreement- Phase 4 Clinical Trial (Medicines)*" should be used.

Refer to http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/

Industry Sponsored Device Trial CTRA:
For industry sponsored device trials the "*The MTAA Standard Clinical Investigation Agreement*" should be used:
This document is available on the Medical Technology Association of Australia (MTAA) website:
http://www.mtaa.org.au/policy-initiatives/clinical-investigations

A Checklist for CTRAs is available at http://www.rah.sa.gov.au/rg/research-governance.php

Other Clinical agreements
All other non standard clinical research agreements e.g. investigator initiated research and collaborative research that involves studies with entities external to the site require a study agreement that will need review by the Research Governance Office.

The final hard copy of the research agreement must be submitted with the SSA Form
Refer to the Research Governance Checklist is available at http://www.rah.sa.gov.au/rg/research-governance.php

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16. Insurance and Indemnity

All research projects hosted by SA Health institutions involving SA Health staff or research staff from outside SA Health must have appropriate insurance and indemnity.

For commercially sponsored studies, the sponsor is responsible for arranging satisfactory insurance cover to indemnify the local site, investigator and participants. This coverage should be verified by the Manager, Insurance Services, SA Health.

For investigator initiated projects undertaken by SA Health researchers, the Coordinating/Principal Investigator must contact the Manager, Insurance Services, SA Health to ascertain whether their project will be covered by SA Health insurance.

Is evidence of insurance cover attached? (e.g. copy of insurance certificate or correspondence from Insurance Services, SA Health)

☉ Yes ☐ No

If a standard clinical trial agreement is used, insurance arrangements are also covered in Schedule 4 of the agreement. For sponsored studies, the Principal Investigator should also supply the certificate of insurance to the Research Governance Office.
For non standard studies and agreements insurance provisions for the study should be discussed with SA Health's Manager, Insurance Services.
Evidence of insurance cover must be submitted with this SSA Form.

A Checklist is available at http://www.rah.sa.gov.au/rg/research-governance.php

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17. Biosafety, Chemical and Radiation Safety

It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation.

If so, evidence of this is required. If "Yes" is marked below against any of these items, appropriate documentation of approval must be attached to this form upon submission.

17a. Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required? ☐ Yes ☐ No

17b. Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? ☐ Yes ☐ No

17c. Will the project require application for a licence to the NHMRC Licensing Committee to conduct embryo research? ☐ Yes ☐ No

17d. For projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State-specific radiation safety approval and registration required? ☐ Yes ☐ No

Institutional Biosafety Committee (IBC). contact: tuckweng.kok@health.sa.gov.au
Refer to: http://www.ogtr.gov.au/

For gene and related therapies refer to: http://www.nhmrc.gov.au/about/committees-nhmrc/human-genetics-advisory-committee-hgac

For licensing committee for embryo research refer to NHMRC Licensing Committee: http://www.nhmrc.gov.au/about/committees-nhmrc/nhmrc-licensing-committee

Radiation Safety Committee contact: peter.collins@health.sa.gov.au

Refer to: http://www.arpansa.gov.au/

If "Yes" is marked against any of the items (17a to 17d), appropriate documentation of approval must be attached to this SSA form upon submission.

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18. Investigational Drugs

18a. Please indicate whether this is a clinical drug trial?

Yes No

18b. Please specify who will be responsible for supplying the investigational drugs to the Principal Investigator. If an arrangement has been made with the local Pharmacy to dispense the investigational drugs, please verify the nature of this arrangement and confirm they have been consulted and agree to perform these services *(note that a signature from the Head of Pharmacy or delegate will be required at the end of this form)*.

Some types of research projects necessitate review and/or approval by the Investigational Drugs SubCommittee details of which are found on the RAH HREC website http://www.rah.sa.gov.au/rec/

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19. Funding

Please specify the nature of the funding to support this project, including the amount of funding and duration; funding source; and any 'in kind' or monetary support being provided by the Site.

Note that endorsement by the relevant Head/s of Department/s at this Site where the research will be conducted is required on this form. This will verify their understanding and approval of research costs and expenditure and: a) funding is available for these purposes; or b) cost recovery processes will be initiated if project expenditure exceeds available funding and resources.

Type of funding	Source of Funding	Amount ($/year or $/participant)
Commercially Sponsored		
Other External Funding *(e.g. research grants)*		
Internal/Departmental Funding		
'In kind' support		

Information should be as accurate as possible, identifying the type, source and amount of funding being made available to support the research over and above those costs associated with standard of care.
For clinical trials please refer to the Clinical Trial Budget Guidelines available at http://www.rah.sa.gov.au/rg/research-governance.php

If costs are not covered by external funding please explain how the RAH / SA Pathology will benefit from this research.
The Research Finance Advisor / Business Manager must sight and consider the budget and any associated costs to the RAH / SA Pathology before giving authorisation.
Contact: for RAH: renalyn.roxas@health.sa.gov.au,
For SA Pathology: edward.wong@health.sa.gov.au or derek.ryan@health.sa.gov.au

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20. Financial Oversight

Please identify who will be locally responsible for the management of funding provided for the project, and what cost centre/s funds will be paid into and drawn from.

Responsible person: **Cost centre/s:**

Provide details of the designated Cost Centre where the funding for the project is being managed by the Department.
Where funds are being managed from another site e.g. university, account details are required for invoicing in order to recoup the associated costs. The RAH / SA Pathology has a responsibility to recover costs associated with research conducted at its facilities and by its staff.

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21. Other Support
Please state whether any additional support will be required to conduct the project at the local site (e.g. loan or use of equipment or other resources). Please indicate whether relevant approvals have been obtained for the additional support / resources.

Use of equipment provided by a Sponsor for a study must be approved by Biomedical Engineering. Appropriate documentation of approval must be attached to this SSA form upon submission.

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22. Checklist

	Coordinator or Investigator (Yes, No, N/A)	**RGO (Yes, No, N/A)**
Have all sections of the form been completed?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has a copy of project advertising been provided?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has evidence of Intellectual Property arrangements been attached?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has a completed CTN or CTX form attached to this submission?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
If a commercially sponsored trial, is the Medicines Australia standard indemnity form (signed by the sponsor) attached?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

If a commercially sponsored trial, is the Medicines Australia standard Clinical Trial Agreement (signed by the sponsor) attached?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Is evidence of insurance cover and indemnification attached?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has evidence of biosafety approval been provided?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has evidence of Radiation Safety been provided?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has a CV been attached for the Principal Investigator?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Have the Head/s of all participating Departments or Services involved in the study endorsed the study?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A
Has the data custodian/s provided permission to allow the study investigator/s to use any data required for the study?	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

The checklist must be completed just prior to final submission

When your SSA Form is finally complete it must have a 'submission code' generated from the Online Forms website.

Then print the SSA form so that the Declarations sections can be completed and signed.
Note they must have original signatures and the same submission code must be on the bottom of each page.

When completing the SSA Form some fields relating to declarations and authorisation are blocked as these are not to be completed online. Signatures required for declarations are obtained on the printed hard copy of the SSA document.

23. Declarations

Please ensure all declarations relevant to this proposal are completed and signed by the relevant authorising officer/s. Original signatures are preferred.

a) Declaration by delegated Department Head/s at the site where the project will be conducted.

- I certify that I have read the project details in this SSA for the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- My signature indicates that I support this research project being carried out using such resources.

Name:

Position / Title:	
Department:	
Signature:	.....
Date:	

Add

Where an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible to. Investigators must not approve their own research on behalf of their Department.

Note that approval from the Head/s of Department/s / Service/s is required, and their signature should appear on this form ("Add" each department / service) to verify their authorisation of the project to be conducted, and that all resources required to complete the project are available or will be made available at the site

If the Head of Department is not available to sign this page after the SSA form is locked (eg will be on leave), they may nominate a delegate to sign in their absence or they may discuss the project prior to their leave and sign a statement of support for the project using similar wording to Declaration 23a.

If the declaration is not signed before they leave, the final locked SSA and the final protocol should be emailed to the Head of Department who may sign the Declaration 23a. The scanned copy of the declaration should then be inserted into the hard copy of the form.

b) Declaration by data custodian/s responsible for managing data access for the databases that will be accessed by the Principal Investigator/Site Coordinator for the purposes of undertaking this project.

- I certify that the Principal Investigator / Site Coordinator responsible for this research proposal has submitted their protocol to my Office, and provisional approval has been granted for them to access the data required.

Name:	
Position / Title:	
Organisation:	
Signature:	.....
Date:	

Add	

If the data custodian is SA Health then please contact the SA Health Ethics committee at hrec@health.sa.gov.au. If the data custodian is a department /organisation within the RAH / SA Pathology, a signature is required by the appropriate authorised person responsible for the database.

If the data custodian is not available to sign this page after the SSA form is locked (eg will be on leave), they may nominate a delegate to sign. If not, the final locked SSA and the final protocol should be emailed to the data custodian who may sign the Declaration 23b. The scanned copy of the declaration should then be inserted into the hard copy of the form.

http://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Publications+and+resources/Policies+and+guidelines

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c) Declaration by Head of Pharmacy at the Site that agreement has been made to dispense the drugs/pharmaceuticals required to undertake this study.

- I certify that the Principal Investigator / Site Coordinator responsible for this research proposal has provided me with a copy of the research protocol, and I have agreed on the basis of satisfactory HREC approval that this Department will dispense the drugs/pharmaceuticals required to undertake this study.

Name:

Position / Title:

Signature: .....

Date:

Contact the Head of Pharmacy at your site.

For the RAH contact: peter.slobodian@health.sa.gov.au
If the Head of Pharmacy is not available to sign this page after the SSA form is locked (eg will be on leave), they may nominate a delegate to sign. If not, the final locked SSA and the final protocol should be emailed to the Head of Pharmacy who may sign the Declaration 23c. The scanned copy of the declaration should then be inserted into the hard copy of the form.

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d) Declaration by Site Coordinator/Principal Investigator

- I certify that all details included in this form are correct and that I agree to undertake this study in accordance with any conditions of approval specified by the relevant HREC, and in accordance

with relevant national and local guidelines, legislation and requirements.

Name:

Position / Title:

Signature: .....

Date:

This must be signed by the Principal Investigator at the site.

If the PI is not available to sign this page after the SSA form is locked (eg will be on leave), a signed letter from the PI stating that they are familiar with the protocol and are able to fulfil all requirements for the conduct of the study specified by the relevant HREC in accordance with relevant national and local guidelines, legislation and requirements. This should be inserted into the hard copy of the form.

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24. Recommendation by Research Governance Officer

The Site-Specific Assessment (SSA) form for this research project has been completed (with all attachments).
SSA authorisation is therefore:

Recommended

Not Recommended

If not recommended, the reasons are as follows:

Name: .....

Position: .....

Signature: .....

Date: .....

This is for the Research Governance office to sign

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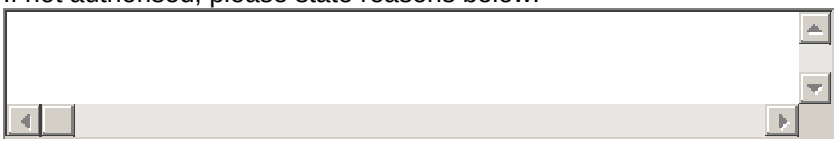
25. Final Authorisation

I hereby confirm that I am (please tick relevant box):

a) satisfied that the proposed research meets all research governance requirements of this site. I therefore authorise the commencement of this project. ☐

b) not satisfied with one or more components of this submission, and am therefore unable to authorise the commencement of this project. ☐

If not authorised, please state reasons below:



Name: .....

Position: .....

Signature: .....

Date: .....

It is only once this final authorisation has been signed that the study has approval to begin.

Submitting the SSA Form to the Research Governance Officer at your site

After generating an SSA 'submission code,' print, sign and provide a hard copy with supporting documents to the Research Governance Office (as described on page 2). If the SSA Form is correctly completed the Research Governance Office will validate the submission.

If the SSA is not validated the Research Governance Office will notify the Principal Investigator and request that the SSA application is completed correctly

The Research Governance Office will assess the SSA Form and ensure all the required documents are completed and will make a recommendation regarding site specific assessment to the CEO or delegate.

Note: Without CEO/delegate authorisation the study cannot commence at the site.
The study can only commence at a site when HREC approval and SSA authorisation is complete.